K02606

FEB 6 2002

ClearMed™

510(k) Summary

Submitter's name and Address:	ClearMedical, Inc. 1776 – 136th Place NE Bellevue, WA 98005 Ph (425) 401-1414 Fax (425) 401-1515
FDA Registration Number:	3017110
Contact Person:	Richard Radford Director of Research and Product Development
Date Summary Prepared:	August 8, 2001
Trade or Proprietary Name:	ClearMedical/Kendall Sequential Compression Device (SCD) Sleeves
Common Name:	Sequential Compression Sleeves
Classification Name:	Sleeve, Limb, Compressible (per 21 CFR section 870.5800)/JOW

Equivalent Device

The ClearMedical/Kendall reprocessed Sequential Compression Device (SCD) Sleeves are substantially equivalent to the Kendall SCD Sleeves, Parts 5329, 5329W, 5330, 5330W, 5345, 5345W, 5480, and 5480W. This determination has been reached based on an evaluation and analysis of the predicate device's technical and promotional labeling and specific bench testing. For all established indicators of substantial equivalence, the ClearMedical devices demonstrated equality in safety and performance.

Device Description:

The ClearMedical/Kendall SCDs are an accessory device to a SCD System which is used for the prevention of deep vein thrombosis and pulmonary embolism. The SCD Sleeve is designed with inflatable bladders that fill with air to

provide compression to the legs. A connector tubing system attaches the SCD to the Controller system.

The SCD Sleeves are latex-free, made of a polyester-cotton fabric. They are designed with velcro hook straps, three bladders and molded polyethylene tubing with a polypropylene snap-lock connector. KendallI has recently changed the device from the color blue to white. ClearMedical will designate the white SCDs with a "w" after the part number (i.e. 5330W).

Intended Use:

The ClearMedical/Kendall SCDs are intended as a single patient use accessory to a Kendall Controller System. The role of the SCD is to reduce the incidence of deep vein thrombosis, reduce pain and swelling after injury and surgery, and increase arterial blood flow. The SCD Sleeves are used in conjunction with the Controller System for non-ambulatory patients in a hospital environment.

Technological Characteristics of ClearMedical and Predicate Devices:

The predicate device and the ClearMedical/Kendall SCDs contain bladders that inflate with air to control circulation of a limb. Attached to the Sleeve is a connector tubing system that connects to the Controller System. In form, the predicate device and the ClearMedical reprocessed SCD are the same.

Technological indicators of substantial equivalence were identified and included methods of infection control, fit/attachment, bladder function, velcro adhesion and connector function.

The predicate device is delivered to the customer labeled 'non-sterile' whereas the ClearMedical/Kendall SCDs are delivered to the customer labeled "High Level-Disinfected". ClearMedical's infection control methods meet or exceed the CDC standards ("Guideline for Handwashing and Hospital Environmental Control", 1985, "APIC Guideline for Selection and Use of Disinfectants") for this class of device.

Summary of ClearMedical/Kendall SCD Performance:

Based on an assessment of bench tests and non-clinical performance data, we believe that in all relevant safety and performance indicators the ClearMedical/ Kendall SCD Sleeves demonstrates substantial equivalence to the predicate devices, the Kendall SCD Sleeves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Mr. Richard Radford
Director of Research and Product Development
ClearMedical, Inc.
1776 136th Place NE
Belluvue, WA 98005-2328

Re: K012606
Trade Name: ClearMedical/Kendall Sequential Compression Device (SCD) Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. Radford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

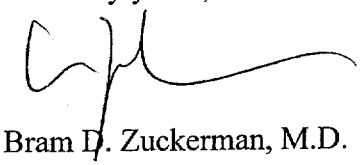
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(K) NUMBER (IF KNOWN): K012606

DEVICE NAME: ClearMedical/Kendall Sequential Compression Devices (SCD)

Part Numbers: 5329, 5330, 5345, 5480, 5329W, 5330W, 5345W, 5480W

INDICATIONS FOR USE:

To reduce the incidence of deep vein thrombosis, reduce pain and swelling after injury or surgery and increase arterial blood flow.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012606

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)